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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
MITCHELL, GREGORY W	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 03/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/049,427	THOR, KARL BRUCE	
	Examiner	Art Unit	
	Gregory W. Mitchell	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *37-42 and 51-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *37-42 and 51-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *06/02/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This Office Action is in response to the remarks and amendments filed June 02, 2004. Claims 19-28, 31-32, 34-36, 43-50 and 55 have been cancelled. Claims 37, 40, and 51-54 have been amended. Claims 37-42 and 51-54 are pending and are examined herein.

In response to Applicant's request, Examiner has sent a copy of the signed IDS dated April 24, 2003. Applicant has re-submitted the IDS originally submitted June 20, 2002 and received June 25, 2002 but not entered into the file. Examiner will sign and return a copy of the IDS with the next Office Action, following entry of the IDS into the file.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 37-42 and 51-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over McMahon et al. (*J. Urology*, 161, 1826-30) and Lane (*J. Psychopharmacology*, 11(1), 72-82) in view of Eli Lily (ZA 9300694) and Robertson et al. (USPN 5135947).

McMahon et al. teaches the treatment of premature ejaculation with oral doses of paroxetine hydrochloride (an SSRI) as needed (Title). The treatment is taught as being

administered on an as needed basis without a priming dose 3-4 hours prior to planned intercourse (Abstract). SSRIs are taught in general to delay orgasm and reduce sexual excitement thereby having a beneficial effect on premature ejaculation (2nd and 3rd paragraphs of p. 1826).

Lane teaches SSRIs for the management of premature ejaculation (Abstract; p. 79). Lane also teaches low dosages of SSRIs administered on an as needed basis prior to intercourse for the treatment of premature ejaculation (p. 79, 2nd col., 1st full paragraph).

Eli Lilly teaches the treatment of premature ejaculation with the SSRIs fluoxetine, dapoxetine, and duloxetine (pp. 1 and 5).

Robertson et al. teaches sluoxetine, serotonin and the compounds as instantly claimed as known in the art as SSRIs (col. 1, lines 15-66; col. 3, lines 35-36; col. 23, lines 1-24 and 48-60; col. 24, lines 46-58). Oral administration of the compounds are taught (col. 19, lines 22-24).

It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the specific compounds of McMahon et al. and Lane with the compounds as instantly claimed because (1) McMahon et al. teaches the treatment of premature ejaculation with various SSRIs; (2) McMahon et al. teaches that SSRIs cause delayed orgasm and reduced sexual excitement thereby having a beneficial effect on premature ejaculation; (3) Lane teaches that SSRIs may be used in the management of premature ejaculation; (4) Eli Lilly teaches the treatment of premature ejaculation with the compounds as instantly claimed; and (5) Roberson et al. teaches the instantly

claimed compounds as SSRIs. Accordingly, absent a showing of unexpected results, it would have been obvious to one of ordinary skill in the art to utilize the known SSRIs of Robertson et al. in the treatment of either McMahon et al. or Lane. One would have been motivated to substitute the SSRIs of McMahon et al. and Lane with the SSRIs as instantly claimed because of an expectation of success in treating premature ejaculation with an SSRI, as taught by both McMahon et al. and Lane.

It would have been obvious to one of ordinary skill in the art to administer the instantly claimed compounds in the dosages claimed and at the times claimed because "[w]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Response to Arguments/Amendments

Applicant's amendments have necessitated the withdrawal of the 35 USC 112(1) and 102 rejections of the Office Action dated December 03, 2003.

Applicant's arguments with respect to the pending claims have been considered but are moot in view of the new ground(s) of rejection. With regard to the current rejections, Applicant's arguments are not persuasive for the following reasons:

Applicant argues, "compounds having SSRI activity are associated with numerous side effects including sexual dysfunction and these effects vary depending on the individual compound, the dose, the distribution of effects between the serotonin and dopaminergic systems, and the plasma levels achieved over time after steady state

pharmacokinetics are achieved." This argument is not persuasive because it does not rebut the fact that both McMahon et al. and Lane teach SSRIs in general for the treatment of premature ejaculation or the fact that it is obvious and within the routine skill of the art to discover optimum or workable ranges when the general conditions are disclosed by the art.

Applicant's reliance on Mos et al. is not persuasive because Mos et al. explicitily teaches that "[m]asculine sexual behavior in rats does not constitute a suitable model to investigate the differential mechanism in sexual inhibition of SSRIs that have been described in human males." See Abstract.

Applicant's reliance on Kennedy et al. is not persuasive because Kennedy et al. teaches only that the sexual dysfunction is *decreased* with favorable drug response not that it was eliminated or reversed.

Applicant argues, "Waldinger et al. showed that paroxetine, fluoxetine and sertraline inhibited ejaculation to different extents while fluvoxamine and mirtazapine did not, and that these effects varied depending on the patient's history of the condition." This argument is not persuasive because Waldinger et al. (*J. Clin. Psychopharmacology*, 18(4), 274-81) teaches that the intravaginal ejaculation latency time (IELT) increased when treated will all SSRIs. Treatment with fluvoxamine was shown to increase the IELT from 20 seconds to 40 seconds – doubling it. See p. 274. Applicant's arguments regarding mirtazapine are not considered because Waldinger et al. (*J. Clin. Psychopharmacology*, 23(5), 467-70) is not considered persuasive because

the reference is not prior art and a person of ordinary skill in the art *at the time of the invention* would not have been known of the teachings found therein.

Applicant further argues, "beginning in 1998 and continuing to the present, the effect of individual SSRI antidepressant compounds on premature ejaculation was not and is not predictable." This argument is not persuasive because the prior art (McMahon et al. and Lane) teaches the use of SSRIs for the treatment of premature ejaculation, in general. Furthermore, Applicant's arguments have only shown that the level of efficacy may have been considered unpredictable by the prior art, not that efficaciousness itself was unpredictable at the time of the invention. Each individual species of the broad genus of SSRIs need not be comparable in efficacy in order to render the known species of that genus obvious for the same utility.

Applicant's arguments regarding Eli Lilly are not persuasive because Examiner is relying on McMahon and Lane in view of Eli Lilly and Robertson et al. In response to applicant's arguments against Eli Lilly individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The references taken together show that it would have been obvious to one of ordinary skill in the art to treat premature ejaculation with the compounds as instantly claimed in the manner as instantly claimed.

Applicant's arguments regarding unexpected results are unpersuasive. Applicant argues, "[t]he two paroxetine references ... disclose as-needed dosing of paroxetine,

but conclude that chronic dosing or as-needed dosing after an initial priming period is more effective than as-needing dosing." This argument is not persuasive because the references do not teach that as-needed dosing is not efficacious, simply that it is not as effective as as-needed dosing following an initial priming dosage. Indeed, McMahon et al. teaches that as-needed dosing with paroxetine hydrochloride, absent a priming dosage, increases mean ejaculatory latency time from 0.3 minutes to 3.2-3.5 minutes.

Applicant's arguments regarding Livni et al. (of record) are moot in view of the instant rejections.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory W. Mitchell whose telephone number is 571-272-2907. The examiner can normally be reached on M-F, 8:30 AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

gwm

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER